IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804
Case No. 17-md-2804

This document relates to:

Judge Dan Aaron Polster

The County of Cuyahoga v. Purdue Pharma, L.P., et al.
Case No. 17-OP-45005

City of Cleveland, Ohio vs. Purdue Pharma, L.P., et al.
Case No. 18-OP-45132

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al.
Case No. 18-OP-45090

Videotaped Deposition of Matthew Strait

Washington, D.C.
May 31, 2019
9:05 a.m.

Reported by: Bonnie L. Russo
Job No. 3404564

Videotaped Deposition of Matthew Strait held at:

Williams & Connolly, LLP
725 12th Street, N.W.
Washington, D.C.

Pursuant to Notice, when were present on behalf of the respective parties:

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ALSO PRESENT:

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Jeff Swaine (Via Teleconference)
Daniel Russo, Videographer
Solomon Francis, IT Specialist

C O N T E N T S

EXHIBITS

EXHIBITS (CONTINUED):

P R O C E E D I N G S

THE VIDEOGRAPHER: Good morning.

We are going on the record at 9:05 a.m. on May 31st, 2019.

Please note that the microphones are sensitive and may pick up whispering, private conversations and cellular interference. Please turn off all cell phones or place them away from the microphones as they can interfere with the deposition audio. Audio and video recording will continue to take place unless all parties agree to go off the record.

This is Media Unit 1 of the video recorded deposition of Matthew Strait, taken by counsel for defendant the matter of In Re: National Prescription Opiate, filed in the United States District Court for the Northern District of Ohio, Eastern Division, Case No. 17-MD-2804.

This deposition is being held at Williams & Connolly, located at 725 12th Street, Northwest, Washington, D.C.

My name is Daniel Russo from the firm Veritext Legal Solutions, and I'm your

videographer today. The court reporter is Bonnie Russo from the firm Veritext Legal Solutions.

Counsel and all present in the room and everyone attending remotely will now state their appearances and affiliations for the record, please.

MR. MASTERS: Brad Masters, Williams & Connolly, for Cardinal Health.

MS. WICHT: Jennifer Wicht, Williams & Connolly, for Cardinal Health.

MR. RUIZ: Anthony Ruiz, Zuckerman Spaeder, on behalf of CVS Indiana, LLC, and CVS Rx Services, Inc.

MS. MONAGHAN: Megan Monaghan from Covington & Burling on behalf of McKesson.

MS. MACKAY: Melanie Mackay from Dechert for Purdue.

MR. PIGGINS: Michael Piggins from Weitz & Luxenberg on behalf of the plaintiffs.

MS. ELLIS: Tiffany Ellis, Weitz & Luxenberg, on behalf of the plaintiffs.

MR. MASTERS: Yeah. Go ahead.

MR. RZODKIEWICZ: Johne Rzodkiewicz, DOJ.

MR. FINKELSTEIN: David Finkelstein, Department of Justice.

MS. SPEARS: Mariama Spears, Drug Enforcement Administration.

MS. BACCHUS: Renee Bacchus, United States Attorney's Office for the Northern District of Ohio on behalf of DOJ and DEA.

MS. WAITES: Natalie Waites on behalf of DOJ and DEA.

MR. STRAIT: And Matthew Strait, DEA.

THE VIDEOGRAPHER: Can everyone remotely please state their name.

MS. MATSOUKAS: Yes. This is Kathleen Matsoukas from Barnes & Thornburg on behalf of H.D. Smith.

MR. BARNES: Robert Barnes, Marc & -- Marcus & Shapira on behalf of HBC Service Company.

MR. BEISELL: Patrick Beisell from Jones Day on behalf of Wal-Mart.

MR. SWAINE: Jeff Swaine --

(Telephone audio malfunction.)

MR. HIMMEL: Brian Himmel, AmerisourceBergen Drug Corporation.

MR. SINDELAR: Jeff Sindelar from Tucker Ellis on behalf of Johnson & Johnson and Janssen Pharmaceuticals.

MR. WALLACE: Matt Wallace of O'Melveny & Myers on behalf of Johnson & Johnson and Janssen.

MR. LAVELLE: John Lavelle, on behalf of Rite Aid of Maryland.

MR. STEPHENS: Neil Stephens for Jones Day for Wal-Mart.

MS. MATIC: Kristina Matic, Foley & Lardner, for Anda.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

MATTHEW STRAIT,

being first duly sworn, to tell the truth, the whole truth and nothing but the truth, testified as follows:

THE VIDEOGRAPHER: You may proceed, Counsel.

EXAMINATION BY COUNSEL FOR CARDINAL HEALTH

BY MR. MASTERS:

Q. Good morning, Mr. Strait.

Thank you for being here today.

A. Good morning.

Q. Have you ever been deposed before?

A. No.

Q. No. This is your first time.

A. Yes.

Q. So just real quick, some ground rules. We'll try not the talk over each other so the court reporter doesn't have too hard of a time.

And if you have any questions about my questions, feel free to ask me.

If -- if counsel objects, you should still answer the question unless -- unless you're instructed not to. Oftentimes these objections are just for the record later.

Any question before we proceed?

A. No.

Q. Okay. How long have you been at the Drug Enforcement Administration?

A. In August it will be 20 years.

MR. MASTERS: I'm introducing what will be marked as -- as Exhibit 1.

(Deposition Exhibit 1 was marked for identification.)

BY MR. MASTERS:

Q. Have you seen this document before?

A. I have.

Q. Do you recognize it as the notice of deposition for today's deposition?

A. Yes.

MR. MASTERS: One more housekeeping document before we get underway.

I'm showing you what has been marked as Exhibit 2.

(Deposition Exhibit 2 was marked for identification.)

BY MR. MASTERS:

Q. Can you identify this document?

A. This was my authorization to participate in the capacity in which I would be authorized to participate today.

Q. And have you seen this document before?

A. I have.

Q. Okay. I'd like to direct your attention to Page 8, the section titled Topic 21, referring to your communications relating to -- relating to and efforts to comply with the reports and recommendations contained in

the following GAO reports.

Do you see that?

A. Yes.

Q. When it says "your," you understand that that is referring to the Drug Enforcement Administration, correct?

A. Correct.

Q. And that today testifying here, you are testifying on behalf of the Drug Enforcement Administration.

A. Correct.

Q. So when we -- so when I refer to "you" in this deposition, unless I refer specifically to you, I'm referring to the Drug Enforcement Administration, correct?

A. Yes.

Q. Do you understand that the subject matter on which you are authorized to be -- to -- to testify today is -- is included here in this section under Topic 21?

A. Yes.

Q. What is your current position at the Drug Enforcement Administration?

A. I am the senior policy advisor to the assistant administrator for the diversion

control division.

Q. And what is your responsibility as the senior policy advisor?

A. I report directly to the assistant administrator and advise him on policy matters that are relevant to the diversion control program, the mission of the program.

Q. Okay. Prior to your current role as senior policy advisor, what was your role at Drug Enforcement Administration?

A. I've had several roles over the last 20 years. And I can get into as much or as little detail as -- as you like about those.

Q. Let's -- let's take the last let's say five years.

A. Okay. I've been back in the diversion control program since June of 2017 serving in the capacity I'm in now.

Prior to that, for two and a half years prior to, I was the section chief for DEA's congressional affairs section and therefore had the liaison responsibilities for the agency with congress.

Q. When you say "liaison responsibilities," can you give me a little

more detail about what that means?

A. Sure. So in -- in congress's role of doing oversight over the federal government, including DEA, my roles would have been prepping witnesses for congressional testimony, providing formal or informal views on legislative proposals that affected DEA, and also working with the interagency on issues of interest in which other agencies might be testifying or working with congress on matters that impact DEA.

Q. The Government Accountability Office is a legislative agency, correct?

A. Yes.

Q. So in your role as liaison between DEA and congress, did your responsibilities intersect with the Government Accountability Office?

A. Yes.

Q. Were -- would you have been aware of investigations and reports of the Government Accountability Office into the Drug Enforcement Administration?

A. Yes.

Q. And what was the nature of your role

as -- as a liaison in that intersection between the Drug Enforcement Administration and the GAO?

A. When these GAO investigations were requested, they were requested by members of congress. And I would not have had a role in the day-to-day interactions with GAO.

But following the release of those reports, they were the subject of congressional hearings that -- that ensued shortly thereafter. And so that would have been my role, is -- is prepping witnesses for that testimony.

Q. Can you explain for the jury what the Government Accountability Office is?

MS. WAITES: Objection. Scope.

And I'll just say, when I say "scope," just to be shorthand, I'm saying it's outside the scope of the 30(b)(6) designation.

MR. MASTERS: Sure.

THE WITNESS: The GAO largely is charged with assisting congress in their oversight role. So in my times -- in many instances, from -- from my experience, GAO reports or requests come from members of

congress as they try to understand better things that they hear from the general public.

BY MR. MASTERS:

Q. In your experience, how does the GAO go about its -- it's role in -- in oversight?

A. I believe they're very methodical. I think they do really good work.

Q. And -- and what kind of work do they -- so you mentioned earlier that members of congress may request the GAO to investigate something.

When you say "they're very methodical," what do you -- what do you mean by that?

A. Just the way they go about doing their business. The work that they do, they generally come in, have a kick-off meeting with the -- the subject of their investigation, the agency. They ask a number of very deliberative questions. They seek responses in -- in certain time frames. And there's oftentimes a very persistent exchange of information throughout their audit period.

They're very good at controlling deadlines and helping congress get their

responses in -- in a timely fashion.

Q. When the GAO investigates let's say the Drug Enforcement Administration and issues recommendations, does the -- does -- does the DEA take those recommendations seriously?

A. Absolutely. Yes.

Q. Does -- does the DEA have an obligation to respond to particular recommendations that the GAO makes?

A. Yes.

Q. Are there internal processes for addressing GAO recommendations?

A. Absolutely. Yes.

Q. As a matter of course -- well, let me ask it this way: What is typical -- what are the kinds of internal processes for responding to GAO recommendations?

A. Well, DEA has a whole GAO audit liaison team whose sole function is to ensure that GAO is getting, one, responses to their questions during the audit time frame when a -- when a report is under consideration; but then also, on follow-up, once recommendations are made, our audit liaison team is consistently working with the program office to what we call

close out a recommendation.

Q. And what does it mean to close out a recommendation?

A. It means to address to the satisfaction of GAO the recommendations that they've made.

Q. Now, typically when the -- when the GAO investigates an issue, they will give the agency an opportunity to respond before releasing their report; is that correct?

A. That's correct.

MS. WAITES: Objection. Vague.

Just make sure I...

BY MR. MASTERS:

Q. In your experience, that is -- that is true of the GAO's handling of investigations relating to the DEA, correct?

A. Yes.

Q. And then the GAO will -- strike that.

The -- the DEA will then have an opportunity to respond, right?

A. Yes.

Q. And the GAO, if there is a response, will respond to the response in their report,

right?

A. GAO takes DEA's response in consideration and may or may not make changes to their final report. But they generally do comment in their report as to their agreement or disagreement with -- with comments made by the -- by the DEA.

(Deposition Exhibit 3 was marked for identification.)

BY MR. MASTERS:

Q. I'm handing you what has been -- hold on a second -- what has been marked as Exhibit 3.

Can you identify this document?

A. This is the GAO's report known in the -- known by GAO as GAO 15471.

Q. And you -- you have seen this report before, correct?

A. Correct.

Q. When did you first become aware of this report?

A. Back in 2015.

Q. That was when the report was issued?

A. Yes.

Q. Were you aware of the -- of the

investigation prior to the issuance of this report?

A. In my capacity in our congressional affairs office, I was aware that the -- the study was being undertaken. But I was not aware of when it was going to culminate, when it was going to be issued.

MR. MASTERS: Okay. Great.

Can we go off the record real quick to address this ELMO issue.

THE VIDEOGRAPHER: We are going off the record.

The time is 9:21.

(A short recess was taken.)

THE VIDEOGRAPHER: We are going back on the record.

The time is 9:24.

You may proceed, Counsel.

BY MR. MASTERS:

Q. Turning to Page 1 of the report -- or I should say the -- the very first page, the summary, the first full paragraph, the second sentence from the bottom states: "Federal internal control standards call for adequate communication with stakeholders."

Do you see that?

A. Second from the bottom. I -- of the first full paragraph?

Q. Yes.

A. "Federal" -- yes.

Q. Does the DEA agree with that statement?

A. Yes.

Q. In this study the GAO was asked by members of congress to review the adequacy of DEA's communications and guidance with distributors and pharmacies about their regulatory responsibilities, correct?

A. And practitioners.

Q. Sorry. And practitioners.

So they were asked to look at the communications and guidance between DEA and distributors, pharmacies and practitioners?

A. Correct.

Q. And to conduct its investigation into the communication and guidance with these registrants, what did the GAO do?

A. They did a --

MS. WAITES: Objection. Vague.

THE WITNESS: They did a survey.

They conducted a survey for each of the registrant populations.

BY MR. MASTERS:

Q. Was that a nationally representative survey?

A. They called it generalizable. They interviewed -- they sent the survey out to 200 distributors, 300 pharmacies and 400 practitioners.

But for a point of consideration, 300 pharmacies, we have about 71,000 pharmacies presently. With our practitioner community, we have 1.7 million prescribers at present. So they -- they did 400. And they -- they used a statistical model to -- to make it generalizable to the public.

Q. And what about with distributors; how many distributors are there?

A. 200 of -- presently -- in the report they refer to 9 -- over 900, I think 945. But on the controlled substance side, we have 750.

Q. Okay. And same -- same with distributors as -- as with pharmacies and -- and practitioners; they used a statistical model to make it generalizable with respect to

distributors, right?

A. That's what's in their report, yes.

Q. They also interviewed 26 national associations and other nonprofit organizations, correct?

A. Correct.

Q. And they interviewed 16 government agencies from four different states?

A. That is correct.

Q. And in addition to the web-based surveys of all those registrants you mentioned, the national associations and the government agencies, the GAO also reached out to DEA for its perspectives on communications and guidance to registrants, correct?

A. That is correct.

Q. I'd like to direct your attention to Page 6 of the report, the full paragraph beginning with "We also obtained."

It -- it states: "We also obtained documents from and interviewed DEA Office of Diversion Control officials who have oversight responsibility for DEA registrants and are engaged in addressing prescription drug abuse and diversion issues to learn about how DEA

interacts with its registrants and other nonfederal stakeholders and to obtain DEA's perspectives on information from our survey results and interviews with nonfederal stakeholders."

Did I read that correctly?

A. Yes.

Q. Is that consistent with the DEA's understanding of GAO's engagement with DEA in the course of this investigation?

A. Yes.

Q. That report indicates that the GAO interviewed DEA Office of Diversion Control officials, correct?

A. Correct.

Q. Who was interviewed?

A. I don't know specifically the names of the individuals that were interviewed, but they would have been senior officials within the diversion control.

At the time it was the Office of Diversion Control. Now they are the Diversion Control Division.

Q. And these senior officials would have had personal knowledge and understanding

of the communications and guidance that DEA had given to registrants in the past, correct?

A. Absolutely. Yes.

Q. It also indicates that -- that GAO obtained and reviewed documents from the Drug Enforcement Administration, correct?

A. Yes.

Q. What documents did they obtain?

A. Well, I -- I believe they were referred to throughout the report -- some of the documents -- they talked about a Know Your Customer document in 2011. And I'm not -- I'm not certain of what other types of documents they would have specifically asked for and reviewed.

Q. One of the issues that the GAO was investigating was the adequacy of DEA's guidance to distributors relating to suspicious order monitoring, correct?

A. Yes.

Q. Did the GAO issue any recommendations concerning DEA's guidance to wholesale distributors relating to suspicious order monitoring and reporting?

A. Let me go back to read the

recommendation.

Recommendation 2 was to --

Q. Can -- before you begin, can you let me know which page you're reading from?

A. Sure. I'm on Page 44 of the report.

Q. Okay. Great. I'm sorry. Please continue.

A. Recommendation 2 was: "Solicit input from distributors or associations representing distributors and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting."

Q. Now, in your understanding of the GAO's report, that recommendation encompassed both additional communications with distributors and additional written guidance, correct?

MS. WAITES: Objection. Misstates the document. Mischaracterizes the document.

THE WITNESS: I just want to go back and read specifically.

"Solicit input and develop additional guidance for distributors."

It doesn't necessarily, as I

understand, separate between whether it be verbal or whether it be in writing.

BY MR. MASTERS:

Q. Okay. Did -- did the report say that some of the distributors wanted more guidance?

A. Yes.

Q. In fact, more than half of the distributors who responded to the open-ended questions in the survey said they needed more communication, information and inter -- interactions with DEA, correct?

A. Yes. I believe that's on Page 26 of the report, if I'm not mistaken.

Q. That is correct. You have a great memory.

In the middle of paragraph beginning with "Furthermore," it says: "Furthermore, in response to an open-ended question about what additional interactions they would find helpful to have with DEA, more than half of the distributors that offered comments said they needed more communication or information from or interactions with DEA."

Did I read that correctly?

A. That -- that looks correct, yes.
Q. Did the GAO say that the DEA was giving more written guidance to pharmacies and physicians than it was to distributors?
A. I think that's a fair characterization. The report discussed the pharmacist manual and the practitioner's manual, which were written publications on the diversion web site. And there is no such manual for DEA registered distributors.
Q. Let's -- let's go ahead and turn to that section of the report. It's one page over on Page 25.
A. Uh-huh.
Q. Would you please read for the record the first two sentences of the second paragraph.
A. "Some survey responses indicate that additional guidance for distributors regarding suspicious orders monitoring and reporting, as well as more regular communication, would be beneficial.
For example, while DEA has created guidance manuals for pharmacists and practitioners, the agency has not developed a

guidance manual or a comparable document for distributors."

Q. Did the GAO conclude that additional guidance for distributors regarding suspicious order monitoring and reporting would be beneficial?

A. Their recommendation is as we had previously discussed.

Q. And -- and the GAO found specifically that that additional guidance would be beneficial, correct?

A. Well, if they are making a recommendation, then they are recommending that the DEA take action on that front.

Q. Okay. Great.

And -- and just going back to Page 25, the first sentence indicates that -- well, I'll -- I'll strike that.

Was the GAO concerned that, in the absence of clear guidance, distributors may be setting conservative thresholds on the amount of controlled substances that they will sell to pharmacies.

MS. WAITES: Objection. Vague. Lacks foundation.

THE WITNESS: I -- I don't want to get into the head of GAO. I actually don't know the answer to your question.

BY MR. MASTERS:

Q. Let's turn to Page 27 of the report, the second paragraph about two-thirds of the way down, beginning with "Additionally."

Do you see that?

A. I do.

Q. Can you read that sentence?

A. "Additionally, in the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers, i.e., pharmacies and practitioners, which can negatively impact pharmacies and ultimately patients' access."

Q. Does the DEA agree with that statement?

A. I would say that this sentence is talking about what distributors told GAO. And I think that G -- we would agree that arbitrary thresholds set by a pharmacy -- or excuse me -- by a distributor could create supply access

issues.

But on the flip side, I would say that those types of arbitrary thresholds could actually create oversupplies as well.

Q. And here the GAO, in -- in response to the surveys, is observing that the thresholds are restricting supply, correct?

A. They're quote -- I -- I take this statement to be quoting from one of the survey respondents. And it's unclear whether -- oh, that was a chain pharmacy corporate office survey.

I was going say I was unclear as to whether it was a -- a distributor or a pharmacy that was actually indicating that.

Q. So the -- so the -- the pharmacy surveys are showing that -- are showing to -- to GAO that these -- that the absence of clear guidance is resulting in distributors setting thresholds that are -- that's restricting the supply of these drugs and ultimately negatively impacting pharmacies and patient access, correct?

MR. SMITH: Objection. Mischaracterizes the document.

THE WITNESS: And I was going to say I -- I would push back on that -- the way that you offered that. Because I think you're inferring that the lack of guidance has resulted in these distributors setting arbitrary thresholds.

That is a business decision that is being made by distributors. And so I can't necessarily say that this document connects one with the other.

BY MR. MASTERS:

Q. So in the GAO's view though, "In the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers," correct?

A. That is a correct repeat of that sentence. But it does -- it's coming from the survey results. So it's coming from, in this case, a pharmacy or a corporate pharmacy.

Q. And the GAO is connecting that to the absence of clear data -- or clear guidance, right?

A. I -- I -- I don't -- I don't

necessarily agree with that assertion.

Q. Okay. GAO was provided -- or GAO provided DEA with a draft of this particular report prior to its publication, correct?

A. Correct.

Q. And Mr. Joseph Rannazzisi responded in a letter on behalf of DEA, correct?

A. That is --

Q. And who --

A. -- correct.

Q. -- who is Joseph Rannazzisi?

A. So Joseph Rannazzisi, at the time this report came out, was the deputy assistant administrator for the diversion control -- or the Office of Diversion Control. So he would have been the person who ran the diversion -- the diversion control program.

Q. And -- and DEA's position was that additional guidance was not necessary?

A. That is correct. DEA explained the multitude in -- of ways in which its already communicated in this case with distributors.

Q. And DEA's position was that the -- the text of the suspicious order regulation itself was sufficiently straightforward,

correct?

A. It had been in place for 40 -- at the time of this publication, probably 45 years; and that it was well understood by our DEA registrant community; and that we did not see a -- a need to expand upon it.

Q. And -- and be -- in part because the DEA's position was that it was sufficiently straightforward.

A. I -- I think that's correct, yes.

Q. And the -- but the GAO found in its survey that many registrants did not feel that it was well understood and, in fact, wanted more guidance, correct?

A. Survey respondents did show that they would like more guidance.

Q. More than half of the distributors who -- who commented on that said -- said that, right?

A. Yeah. And I -- I want to make a point of clarification on that.

If -- if we -- if we go to Table 21, which is something that I think is -- is necessary to point out -- remember we have 750 controlled substance distributors at present.

The survey asked a number of questions. And then it's asked some open-ended questions. And you're obviously referring to the open-ended questions.

But like we said at the outset, they sent 200 surveys out to distributors. They received 77 responses on a question to distributors about guidance that -- that DEA provided.

And to your point, there was a portion of those 77 who asked for more guidance.

Q. Fair enough.

The DEA also told the GAO that, short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers, correct?

A. Can -- can you point that out on the --

Q. Sure. Page -- give me one second. It's -- it's in the -- the letter that Joseph Rannazzisi sent. On Page 81 of the report,

Page 5 of the letter.

A. Okay.

Q. Second -- or first full paragraph, last sentence.

Would you read that for the record?

A. Sure.

"Short of providing arbitrary thresholds to distributors, DEA cannot provide more specific suspicious orders guidance as the variables that indicate an order is suspicious are very fact-intensive and differ from distributor to distributor and from customer to customer."

Q. Can you explain what that means?

A. Yes, I -- I can. So DEA -- we have long understood that distributors would like nothing more than for DEA to tell them how much an average pharmacy should be able to purchase. And then they could use DEA's assessment as a -- to set a threshold. And that would give them the opportunity to, you know, basically say that that's a DEA-established threshold.

What we've said is, with 71,000 DEA-registered pharmacies and 18,000 hospitals and 1,700 narcotic treatment programs, all of

the types of customers that distributors sell to, we can't do that.

Because, quite frankly, the circumstances on what is appropriate for one pharmacy may be completely different than the requirements of another pharmacy. It's based on the population. It's based on the types of patients that are bringing prescriptions in to pharmacies or -- or being dispensed or administered at hospitals. It's the based on a number of different factors.

And pharmacies that are around the corner from one another may have vastly different profiles that are acceptable.

So DEA feels very strongly that that is something that only a distributor can know. Because a distributor is going to have much more of a working knowledge of who their customers are, more so than DEA.

And I would argue that, if you end up setting an arbitrary limit on how much can be distributed by -- if DEA were to do this, you could inadvertently create a shortage of a situation if that amount is not sufficient. Or on the flip side, if the -- if that number is

too high, you could actually create overages; and therefore, DEA is of the opinion that increases in availability could have the unintended consequence of increasing diversion and abuse.

Q. And so DEA was not willing to provide additional guidance -- more specific suspicious order guidance than what is in the regulation itself?

A. At the time that this letter went out, that is accurate.

Q. And the regulation itself defines a suspicious order as an order of unusual size, deviating substantially from the normal pattern, or an order of unusual frequency, correct?

A. That's sounds correct.

Q. And -- and the regulation does not say what an unusual size means, correct?

MS. WAITES: Objection. Scope.

THE WITNESS: It does not go on to define any of those terms.

BY MR. MASTERS:

Q. And at the time that this letter was written, the DEA had not provided additional

specific written guidance as to what unusual size, frequency or pattern means, correct?

MS. WAITES: Objection. Scope.

THE WITNESS: That is correct. Although I want the qualify that by saying nothing as it pertains to what I think they distributors wanted, which was something in writing.

DEA was certainly increasing its liaison opportunities with the distributor community in terms of distributor conferences that we held in '13, '15 and '16; kind of one-on-one engagements through what's known as our distributor initiative, which we initiated back in 2011 and continues to this day.

And so I think, with a very limited registrant population -- they represent, what, 0.06 percent of our DEA registrant population, if not slightly less -- that the one-on-one interaction we believe in -- in a -- in a person-to-person, face-to-face environment is -- is better.

Q. But no written -- but you mentioned no additional written guidance, correct?

A. At the time of this letter, no.

Q. Okay. In its report GAO responded to the DEA's letter, right?
A. Can you repeat the question.
Q. In -- in its report, the GAO addressed what the DEA said in its letter, correct?
A. Yes.
Q. And notwithstanding the DEA's comments on the draft report, the GAO still found that the DEA could provide additional guidance to distributors, right?
A. Can you point to what -- what you're referring to?
Q. Turning to Page 44, it says: "Agency comments and our evaluation."
A. Yeah.
Q. Do you see that?
A. Yes, I do.
Q. And so this is the section in which the GAO is responding to the Department of Justice's response, correct?
A. Yes.
Q. And on page 45, it acknowledges the -- the DEA's concerns about our second recommendation to solicit input from

distributors or associations representing distributors and to develop additional guidance for distributors, right?

A. Yes.

Q. Then on page -- well, let's -- let's walk through some of these.

It goes on to say that -- to repeat what we just talked about, that short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance, right?

A. Yes.

Q. The -- the GAO is summarizing the DEA's letter.

A. The DEA's comment. That's correct.

Q. And it says: "Instead, DEA highlighted regulations that require distributors to design and operate systems to disclose suspicious orders," right?

A. Correct. Yes.

Q. And it says: "However, according to DEA's customer service plan for registrants, DEA is responsible for developing guidance for registrants regarding the CSA and its regulations. And the agency was able to create

such guidance for pharmacy and practitioner registrants."

Did I read that correctly?

A. That is correct.

Q. Turning to Page 46, that same paragraph toward the end, the GAO -- well, would you please read the sentence beginning with "Therefore."

A. "Therefore, we continue to believe that DEA could provide additional written guidance for distributors that could be more widely accessible to all distributor registrants."

Q. So here the GAO is not only recommending additional guidance but additional written guidance, correct?

A. Correct.

Q. And the GAO had -- had found that the DEA has created guidance manuals for pharmacists and practitioners like doctors but not distributors, right?

A. Yes.

Q. Is it true that the DEA had created manuals for pharmacists and practitioners about their regulatory obligations?

A. Yes.

(Deposition Exhibit 4 was marked for identification.)

BY MR. MASTERS:

Q. I'm showing you what has been marked as Exhibit 4.

Why don't you keep that report close and hand. Because we'll --

A. Come back to it?

Q. -- be coming back to it. Thanks.

Can you identify this document?

A. This is DEA's pharmacist manual.

Q. So this is one of the -- one of the two manuals that we just spoke about that DEA has provided to -- to registrants but not to distributors, correct?

A. Yeah. We would not provide this to distributors. But yes, we -- this is a document that is provided for the benefit of our 71,000 retail pharmacies nationwide.

Q. And if we turn to -- just after the -- the table of contents, at -- at -- let's see. Where is this? Actually, just before the table of contents. This is the very second page of the document -- notes that: "This

manual has been prepared by the Drug Enforcement Administration Office of Diversion Control as a guide to assist pharmacists in their understanding of the federal Controlled Substances Act and its implementing regulations as they pertain to the pharmacy profession."

Did I read that correctly?

A. That is correct.

Q. And this manual is a total of -- let's see -- 79 pages, correct?

A. Correct.

Q. And it provides additional written -- additional written guidance to pharmacists about how they can comply with the CSA and its regulations in -- in the course of their profession, correct?

MS. WAITES: Objection. Scope.

THE WITNESS: It is a summary document of the rules and regulations pertaining to DEA registrants.

BY MR. MASTERS:

Q. And it explains those -- those -- those regulations and -- and gives them guidance on how to follow them in their professional practice, correct?

MS. WAITES: Objection. Scope.

BY MR. MASTERS:

Q. That's what we just read.

A. Yeah. I -- I'm -- I'm -- that's fine. Yes. I agree.

Q. Okay. And is it also true that, at the time of this report, DEA had not developed a guidance manual or comparable document to the one we just looked at for distributor registrants?

A. Yes.

Q. And GAO here recommended that you create one.

MS. WAITES: Objection. Mischaracterizes the document.

THE WITNESS: GAO recommended additional written guidance or additional guidance. And that is something that is currently required in order to close out this remaining open recommendation.

BY MR. MASTERS:

Q. And has DEA provided that to distributors yet?

A. It's deliberative. We are actually -- as you may know, in fall of 2017,

DEA -- the Department of Justice added to its unified agenda suspicious order reporting as a regulatory priority. So there will be written guidance in the form of a notice of proposed rule making published in the Federal Register. And that's an effort that was added to the unified agenda in the fall of '17.

Q. And has -- has -- as of today, what is the status of this recommendation from the GAO?

MS. WAITES: Objection.

To the extent it calls for privileged information, you cannot respond. But if you can respond without disclosing privileged information, that's fine.

THE WITNESS: I will be very careful. Because obviously, as a deliberative document, we can't talk about the details of what may or may not be in it. But it does remain under review within the executive branch.

BY MR. MASTERS:

Q. So as of today, DEA has not provided to -- to -- to distributors the additional written guidance called for by the GAO in this

report?

A. Beyond the stuff that we've already discussed pertaining to our continued efforts to work with registrants directly, put -- barring that aside, yes.

The reg -- the regulation, once published, we understand from GAO, will be the basis by which this recommendation can be closed.

Q. And just to be clear, as of today, the DEA has not provided the additional written guidance that GAO recommended to distributors as of today, correct?

MS. WAITES: Objection. Asked and answered.

THE WITNESS: It remains an open recommendation.

MR. MASTERS: Okay. Could we take a quick break?

MS. WAITES: Yes.

THE VIDEOGRAPHER: We are going off the record.

This is the end of Media Unit No. 1.

The time is 9:59.

(A short recess was taken.)

THE VIDEOGRAPHER: We are back on the record.

This is the beginning of Media Unit No. 2.

The time is 10:14.

You may proceed, Counsel.

(Deposition Exhibit 5 was marked for identification.)

BY MR. MASTERS:

Q. I'm showing you what has been marked Exhibit 5.

Can you identify this document?

A. Yes. This is GAO 16-737T. This was congressional testimony provided by Diana Maurer to the senate Homeland Security Committee, I believe -- I'm sorry -- Committee of the Judiciary.

Q. And -- and -- sorry.

And who is Diana Maurer?

A. Her title here is director for homeland security and justice at the GAO.

Q. And she was providing testimony to congress on behalf of the GAO regarding prior GAO reports and recommendations for the Drug Enforcement Administration, correct?

A. Correct.
Q. Were you aware of this testimony when it was given?
A. Yes. Because DEA had a witness as well.
Q. Okay. Did you review this report in preparation for today's testimony?
A. I did.
Q. Turning to Page 19. Ms. Maurer, on behalf of the GAO, is commenting on the DEA's efforts to comply with the recommendation in the report we were discussing a moment ago, correct?
A. Could you point to the paragraph?
Q. The paragraph -- the second full paragraph.
A. The second full paragraph. I have --
Q. So beginning the sentence "In commenting" --
A. "In commenting."
Q. -- "on our report."
So I'll ask my question again.
Ms. -- Ms. Maurer, on behalf of the GAO, is commenting here on the DEA's efforts to

comply with the recommendation in the report we were discussing a moment ago, correct?

A. Correct.

Q. And it notes that: "In April 2016, DEA provided information about ongoing efforts to educate distributors about their roles and responsibilities for monitoring and reporting suspicious orders, such as their distributor conferences, and noted that it plans to host a yearly training for distributors."

Did I read that correctly?

A. That is correct.

Q. Would you please read the next two sentences?

A. "However, DEA" noted -- "However" -- excuse me.

"However, DEA did not mention any plans to develop and distribute additional guidance for distributors. We continue to believe that a guidance document similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their role and responsibilities under the CSA."

Q. Is it true that at that time the DEA

had not mentioned any plans to develop and distribute additional guidance for distributors?

A. My recollection is that the correspondence that she's referring to in April 2016, we were recommending closing the recommendation based on some of the conferences that we were hosting; and that that -- we thought that that was sufficient.

And as she had stated in her testimony, and as it became understood shortly thereafter, in order to close the recommendation, we understood that we would need to be doing something in writing.

Q. Okay. When you say as it was made clear shortly thereafter, that in order to close the recommendation, you would -- the DEA would need to provide something in writing, what are you referring to?

A. So as we had discussed, our GAO audit liaison team had regular correspondence with GAO with the goal of closing out recommendations. And that correspondence is in writing. And it's relatively routine.

So I am recounting my review of

those internal communications that went back and forth to GAO where we had actually, on more than one occasion, sought to close this recommendation based on the -- the conferences that we just referenced.

And it -- that's why I say it became clear that they wanted something in writing.

(Deposition Exhibit 6 was marked for identification.)

BY MR. MASTERS:

Q. I'm showing you what has been marked as Exhibit 6.

Can you identify this document?

A. Just as I had previously stated, this is an example of the types of correspondence that DEA -- in this case this came from our chief compliance officer, who had the O -- the GAO audit liaison team underneath her. This would have been that -- that routine correspondence as the agency works the closeout recommendations.

Q. And specifically this is called a -- a -- a Drug Enforcement Administration status report, correct?

A. Yes. They are referred to as status

reports.

Q. And in this status report, DEA is providing an update on actions taken to address the GAO's report and recommendations, correct?

A. Correct. At this time in June of 2017, none of the recommendations had been closed.

Q. And as you indicated a moment ago, Recommendation No. 2, which is what related to guidance to distributors, had not been closed because the GAO felt that the DEA needed to provide written guidance in order to close the recommendation, correct?

MS. WAITES: Objection. Misstates prior testimony.

THE WITNESS: So this is the -- this is -- this response on Page 2 represents the agency's discussion about the regulatory drafting efforts that it was undertaking.

BY MR. MASTERS:

Q. My -- my question is a little different.

You -- you mentioned a moment ago that the -- that, as of June 2017, none of the recommendation had been closed.

And I -- I'm -- I'm ask -- asking if that -- well -- that that is because, in the GAO's view, the -- the DEA needed to provide written guidance, and the DEA had not done that as of this point, correct?

A. That's -- my understanding is that the GAO did not -- declined to close out Recommendation 2 based on previous status reports.

Q. Got it.

So let's turn to the DEA's response to Recommendation No. 2.

Here the DEA states that it is: "reviewing and revising current regulations regarding suspicious orders, which will include guidance for distributors regarding their roles and responsibilities for monitoring and reporting."

Did I read that correctly?

A. That is correct.

Q. So in response to the GAO's recommendation to develop additional written guidance, DEA was not proposing to develop a guidance manual or comparable document to the one that exists for pharmacists and

practitioners, correct?

A. I think that gets a little bit at some of the predecisional stuff that I have to raise some concerns. I -- I don't really feel I can answer that question.

Q. In -- in the DEA status report, it mentions nothing -- in this document, the DEA mentions nothing about plans to develop a guidance manual or comparable document to the pharmacist and practitioner manual, correct?

A. A plain reading of that first sentence talks about regulations.

Q. Instead, in order to satisfy the GAO's recommendation to develop additional written guidance, DEA planned to revise the existing suspicious order regulations, correct?

MS. WAITES: Objection to the extent it calls for privileged information.

THE WITNESS: Clearly the -- the -- the clear language says that "we are seeking to revise our regulations."

BY MR. MASTERS:

Q. And that these new regulation would include additional guidance for distributors regarding their roles and responsibilities for

monitoring and reporting, correct?

A. A Federal Register Notice that seeks to revise regulations on the books for 45 years would obviously have to include extensive information, which is often considered as the public considers how they want to comment. In -- in this case, the -- the public would be our DEA registered distributor.

Q. And the distributors would have an opportunity to comment on this additional guidance, correct?

A. Absolutely. All formal rule making takes place under notice and comment rule making procedures. So the public will absolutely have an opportunity to comment.

Q. And that -- and given that -- and this is the first time that these regulations would be revised, correct?

A. Based on --

MS. WAITES: Objection. Scope.

THE WITNESS: I was going to say, based on my understanding -- and I didn't do a fulsome analysis of the regulatory history on this. But my understanding is -- is that these regs came into play somewhere between '70 and

'73 and have not really been revised in our regulations since that time.

BY MR. MASTERS:

Q. And the next sentence indicates that a preliminary draft of proposed regulations has been written and is pending editing, review and approval by management within the diversion control division, correct?

A. That is what it says, yes.

(Deposition Exhibit 7 was marked for identification.)

BY MR. MASTERS:

Q. Showing you what has been marked as Exhibit 7.

Can you identify this document?

A. This appears to be another status update from our audit liaison folks to GAO dated February 20th, 2018.

Q. So this is a -- another status report --

A. Correct.

Q. -- similar to the one we just reviewed, correct?

A. Yes.

Q. If -- if we turn to the second page

of the letter, which is -- which contains DEA's response regarding the second recommendation, it now notes that the DEA reviewed and revised the current regulation regarding suspicious orders, correct?

A. Correct.

Q. So before it was the DEA is reviewing and revising, and now it's in the past tense, right?

A. Correct.

Q. And the -- I guess I should have asked when was this letter written?

A. It was written February 20th of 2018.

Q. And as of February 20th, 2018, when was the revised regulation on track to be published in the Federal Register?

A. The revision of the current regulation regarding suspicious orders is on track to be published in the Federal Register by the end of the third quarter for fiscal year 2018. So that would be June 30th, 2018.

Q. And -- and what does -- what does it mean to be -- for a regulation to be published in the Federal Register?

A. That means -- to us it mean a notice of proposed rule making would be ready to be published for public comment on or before that time frame.

Q. That still has -- as of today, sitting here today, the revised regulation that the DEA indicated was on track to be published by the end of the third quarter fiscal year 2018, June 30th, still has not been published for -- in the Federal Register, correct?

A. Yes. If -- if we go back to Exhibit 6, I like DEA's response. Because the last two or three sentences to Recommendation 2 talks about some executive orders that present a, quote, potential obstacle to publication.

"These new executive branch directives may restrict the promulgation of new regulations or may delay the approval process for any new regulation. These directives include January 20th, 2017, White House memorandum and February 2nd, 2017, Office of Management and Budget memorandum."

Q. Okay. So -- so those were potential obstacles.

A. Correct.

Q. And in -- in that -- in that update, you wrote: "Absent these potential obstacles, DEA anticipates the additional review, notice, comment and final publication in the Federal Register will be completed by the end of the third quarter fiscal year 2018."

A. I think what we were trying to say is there's a qualifier.

Q. Sure.

A. If -- absent these kind of interagency or White House directives, we could do it by then. However, as -- as -- where you're going with this question, I just want to say that that is a -- a reasonable -- excuse me -- that is a cause for why there's been delays?

Q. In -- in your next letter you don't mention any of those obstacles.

A. Correct.

Q. You instead say that it's on track to be published, right?

A. Correct.

Q. And in August of 2018, the DEA provided GAO with an additional update indicating that the regulation would not be

published at the end of the third quarter fiscal year 2018, correct?

MS. WAITES: Objection. Lacks foundation.

THE WITNESS: Yeah. I -- I would need to see that.

MR. MASTERS: Sure.

(Deposition Exhibit 8 was marked for identification.)

BY MR. MASTERS:

Q. Showing you what has been marked as Exhibit 8. It's a -- a double-sided document.

The Bates stamp for this document is US-DEA 00026833, correct?

A. Correct.

Q. Can you identify this document?

A. This is taken from the GAO's web site. And it represents a summary and status of reports and open recommendations.

Q. And specifically the status report -- the status of -- that the GAO is referring to here is the status of recommendations relating to the 2015 report that the DEA -- that more DEA information about registrants' controlled substances roles could improve their

understanding and help ensure access, correct?

A. Correct.

Q. At the bottom there, it appears that there is a table with the column on the left describing the recommendation and the column on the right describing the status and comments from GAO; is that correct?

A. Yes.

Q. And the second recommendation, which again is the one relating to distributors, appears to cover the end of the first page and onto the second page, right?

A. Yes.

Q. And at this point, the -- the GAO's web site indicates that the status of that second recommendation is open, correct?

A. Yes.

Q. And in the -- in the GAO's comments, it states that: "In February 2018, DEA reported that the agency had reviewed and revised the current regulation regarding suspicious orders and that the revised draft rule was undergoing internal DEA review. DEA reported in August 2018 that they anticipated sending the draft rule to the Department of

Justice's Office of Legal Policy by the end of the first quarter of fiscal year 2019."

Did I read that correctly?

A. That is correct.

Q. What does it mean to send a regulation to the Department of Justice's Office of Legal Policy?

A. As part of our -- as part of the regulatory drafting process, we always like to make sure the public knows that it is not DEA's ability to just publish something on its own. There is often -- or not often -- in every instance extensive collaboration.

That collaboration first takes place with the Department of Justice, which is our parent organization. And then there is interagency coordination that's facilitated by the Office of Management and Budget, which is OMB.

That OMB review is going to be reviews by agencies that would be involved, like the Department of Health and Human Services in the case of controlled substance regulation.

So our -- this update is indicating

that, by the end of the first quarter, we had hoped to have that draft sent to the Department of Justice.

Q. And --

A. And specifically the Office of Legal Policy, who oversees the reg drafting efforts for all the subcomponents within the Department of Justice.

Q. Thank you.

And that is a step that takes place prior to final publication in the Federal Register, correct?

A. Absolutely. It takes place prior to publication of the notice. And it takes place prior to the publication of a final rule.

Q. So here in the August 2018 update that is being described by the GAO, the DA -- the DEA is suggesting that it is no longer on track to publish the regulation in the Federal Register by the end of the fiscal year 2018, correct?

A. That's correct.

Q. In fact, now it would be not until the first quarter fiscal year 2019 that the regulation would even be delivered to the

Office of Legal Policy, right?

A. That's correct.

Q. Since -- since -- well, so here we are today, the second quarter of 2019, May 31st.

Has the DEA sent the regulation to the Office of Legal Policy?

MS. WAITES: Objection.

If it's privileged, do not respond.

THE WITNESS: Yeah. I -- I -- I don't -- that's going to get into deliberative process. And I don't feel comfortable responding to that question.

BY MR. MASTERS:

Q. Okay. As of now, the second quarter of 2019, May 31st, and -- and almost four years after the GAO recommended that the DEA provide additional written guidance to distributors, has the DEA published a revised regulation in the Federal Register?

A. No.

Q. Has the DEA published a guidance manual or comparable document to the one that exists for pharmacists and practitioners?

A. No.

MR. MASTERS: We could go off the record real quick just to make sure that I don't have any more questions. But I think I might be done.

THE VIDEOGRAPHER: We are going off the record.

The time is 10:36.

(A short recess was taken.)

THE VIDEOGRAPHER: We are back on the record.

The time is 10:57.

You may proceed, Counsel.

MR. MASTERS: Mr. Strait, at this time I have no further questions. Thank you for your time.

THE WITNESS: Thank you.

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MS. ELLIS:

Q. Good morning, Mr. Strait.

A. Good morning.

Q. My name is Tiffany Ellis. I represent the plaintiffs in this case.

I just have a few follow-up questions for you this morning.

A. Okay.

Q. I want you to flip to the back page of Exhibit 3, please. Well, I guess the last page, to be technical.

The first section under that -- I'm at page -- it reads "The GAO's Mission."

Could you read that for me, please.

A. Sure.

"The Government Accountability Office, the audit evaluation and investigative arm of congress, exists to support congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations and other assistance to help congress make informed oversight, policy and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity and reliability."

Q. Would you agree that that's the mission of the GAO?

A. Yes.

Q. Essentially it's to -- it's the

audit, evaluation, investigative arm of congress; is that right?

A. Yes.

Q. The GA -- GAO is not responsible for enforcing the Controlled Substances Act, is it?

A. No.

Q. And when the GAO did this report that we've been talking about today, Exhibit 3, it wasn't looking at whether registrants were in compliance with the Controlled Substances Act, was it?

A. No.

Q. It wasn't looking at whether those registrants have reported suspicious orders to the DEA?

A. No.

Q. It wasn't looking at whether registrants had maintained adequate suspicious order monitoring systems, was it?

A. No.

Q. Would you agree that, whether registrants do these things, such as report suspicious orders and maintain adequate suspicious order monitoring systems, relate to whether and -- whether or how well the DEO --

DEA can do its job in stopping diversion?

MS. WAITES: Objection. Scope.

MS. MONAGHAN: Objection to form.

BY MS. ELLIS:

Q. I'd like to direct you to Page 77 of the report, Exhibit 3, and No. 1 of the letter there.

Could you read the first sentence of that paragraph, please.

A. Of recommend -- of the first comment that DEA made or the first sentence of the first paragraph?

Q. I'm looking specifically at Page 77, the letter to Linda Kohn dated May 25th, 2015 --

A. Uh-huh.

Q. -- following "With respect to the G" -- "GAO report, DEA wishes to emphasize the following important facts."

A. Yep. Okay.

And read No. 1?

Q. Yes, please.

A. DEA's Office of Diversion Control is responsible for administering and enforcing the provisions of the CSA as they pertain to

ensuring the availability of controlled substances for legitimate uses while preventing their availability for diversion. The office is not charged with reducing the illicit demand for controlled substances."

Q. Would you agree that that's the responsibility of the DEA's Office of Diversion Control?

MS. MONAGHAN: Object to form.

THE WITNESS: Yes.

BY MS. ELLIS:

Q. What is the role of the DEA?

MS. WAITES: Objection. Vague. Scope.

MS. MONAGHAN: Object to form.

BY MS. ELLIS:

Q. Let me direct you to Page 67 of the report, Exhibit 3.

A. Sorry. What page?

Q. Page 67.

A. Okay.

Q. I may have the may -- wrong reference here.

But would you agree that the DEA's role is the -- is the primary agency

responsible for coordinating the drug enforcement activities of the United States?

A. As it pertains to pharmaceutical drugs containing controlled substances, yes.

Q. It's a law enforcement agency?

A. It is.

Q. Can the DEA take administrative enforcement actions against registrants?

MS. WAITES: Objection.

MR. MASTERS: Objection. Scope.

MS. WAITES: Scope.

MS. MONAGHAN: Object to form.

THE WITNESS: Yes.

BY MS. ELLIS:

Q. You were asked some questions earlier about the difference between pharmacies and distributors. I want to direct your attention back to that portion of your testimony.

Do you recall?

A. Yes.

Q. Do you know how many registrants there are total?

A. Currently we have 1.815 million registrants.

Q. Do you know how many of those are pharmacies?

A. Approximately 71,000.

Q. Do you know how many of those are distributors?

A. Right now -- I think I said 750, but it might be 715. But it is somewhere between 715 and 750.

Q. 715 to 750 distributors and 71,000 pharmacies.

Does the number of distributors versus the number of pharmacies affect the way the DEA communicates with each of those different groups of registrants at all?

MS. WAITES: Objection. Scope.

MR. MASTERS: Objection. Form.

THE WITNESS: Yes.

BY MS. ELLIS:

Q. How so?

A. Obviously, with a -- with 1.8 million registrants, DEA has limited resources, and it does need to think about how best to prioritize those resources.

With our -- that portion of our drug supply chain that handle the largest volumes of

controlled substances, i.e., our manufacturers and our distributors, our engagement with them tends to be more in person, one-on-one, and -- and very much routine in terms of the frequency by which we conduct audits and inspections of those registrants.

And because of sheer numbers, our guidance to those other portions of our registrant community that are larger, i.e., pharmacies, and prescribers, we do have to rely more on providing them guidance on our diversion control web site. And of course we do still engage with them in person by offering all sorts of different training opportunities.

Q. So larger numbers of registrants require greater efforts?

MS. MONAGHAN: Objection.

MS. WAITES: Objection. Scope.

MS. MONAGHAN: Object to form.

MS. ELLIS: Let's me rephrase.

BY MS. ELLIS:

Q. Let -- let's go to the -- Page 2, the summary, I guess, of Exhibit 3.

What GAO recommends, this first sentence on the bottom-left corner: "GAO

recommends that DEA takes three actions to improve communication with" a -- "with and guidance for registrants about their CSA roles and responsibilities."

A. Sorry. Did you say page --

Q. The summary page.

A. Oh, the summary page.

Q. Yes.

A. Okay. And I'm sorry. Where was that directive?

Q. Just what GAO recommends.

A. Oh, yes.

Q. You would agree that this report is focused on guidance for registrants about their CSA roles and responsibilities, correct?

A. Yes.

Q. And your testimony today has been focused on this report, right?

A. Correct.

Q. Is the nature of the responsibility for pharmacies different than that for distributors under the CSA?

MS. WAITES: Object to form. Scope.

MS. MONAGHAN: Objection. Scope.

MS. WAITES: Calls for legal

conclusion.

BY MS. ELLIS:

Q. Are you aware if -- are you aware if pharmacies and distributors are subject to different regulations under the CSA?

MS. MONAGHAN: Object to form.

MS. WAITES: Objection. Scope. Calls for legal conclusion.

THE WITNESS: Yes.

BY MS. ELLIS:

Q. Are you aware whether pharmacies have different reporting requirements to the DEA than distributors?

MS. MONAGHAN: Object to form. Scope. Calls for legal conclusion.

MS. WAITES: Object to scope.

THE WITNESS: I am familiar with the fact that all registrant classes have different requirements in terms of reporting and recordkeeping. So the requirements on one class of registrants, i.e., distributors, is different than the requirements for another class, pharmacies.

MS. ELLIS: Earlier you discussed some of the things that the DEA -- some of the

actions that the DEA had taken in response to the GAO's report. I want to ask you some additional questions about what the DEA -- DEA had done after this report at -- was issued.

I'm marking for the record Exhibit 9.

(Deposition Exhibit 9 was marked for identification.)

MS. WAITES: Do you have a copy for me?

MS. ELLIS: I'm sorry. I think I just handed the other two down that way. I apologize.

BY MS. ELLIS:

Q. Exhibit 9 is a e-mail that I believe you reviewed in advance of today's deposition. The Bates number is cut off a little at the bottom, but for the record it's US-DEA-00026799.

Do you recall reviewing this document?

A. Yes.

Q. On the second page of the document, it appears to be a letter.

What is this letter?

A. This would have been one of the status update letters from our GAO audit liaison section to GAO. And this one was dated April 27th, 2016, which means that it would have been very -- within a year or right around a year after the report came out.

Q. Is this the first status update letter that you're aware was issued following the report?

A. No. Actually, the -- there is a reference to the -- in the first paragraph to a status response congressional letter dated September 21st, 2015.

And what that means to me is that congress probably wrote to ask about the status. And in DEA's response to congress, it would have sent a CC copy to GAO.

Q. So that -- that would have been different than this type of letter?

A. Correct. But it could have been similar.

Q. Similar but not directly to GAO.

Okay. I want to direct you to the next page of the document, Section 2.

What is your understanding of the

DEA response in Section 2?

What is this in response to?

A. Page 2, this is DEA's response to Recommendation 2 about guidance for -- for distributors and those associations representing distributors on their suspicious order monitoring reporting obligations.

Q. You were asked a lot of questions this morning about whether the DE -- DEA had issued any written guidance to distributors between the time that the report was issued and today.

Does this section describe other actions that the DEA took to educate distributors about their responsibilities under the CSA?

A. Yes.

Q. And what are some of the actions that the DEA took during this time frame as outlined in this letter?

A. So the first paragraph talks about DEA's distributor conference, which it held in 2013, and then, as indicated here, held in 2015 and 2016.

The -- obviously what we go on to

say is that information provided during these conferences are published on DEA's web site.

The third paragraph talks about DEA's work with the National Association of Boards of Pharmacy and a number of other stakeholder groups, which includes some associations representing various aspects of our registrant population on a consensus document entitled "Stakeholders, Challenges and Red-Flag Warning Signs Related to Prescribing and Dispensing of Controlled Substances."

Q. Were all of these efforts by the DEA to comply with the GAO's recommendation to provide distributors further guidance under the CSA?

A. Yes.

Q. Were some of these written?

A. To the extent that the distributor conference presentations were -- are generally PowerPoint presentations and therefore are -- are written documents, yes.

And the -- the NABP document, I actually did take a look at that. I did not see where DEA was actually noted as an author, which is the reason I didn't mention it during

my -- my remarks earlier. So that I'm -- I'm not certain I can say with certainty that that would have constituted written DEA guidance.

Q. You mentioned, I think, in your earlier answer something about a distributor initiative and working directly with distributors.

Do you recall that testimony?

A. Absolutely. Yes.

Q. Would -- would this be a part of that?

A. So actually the distributor initiative is separate from the issues that are outlined in this response. But certainly DEA has indicated that one of the main ways in which it interacts with the distributor community is through what's called the distributor initiative, which I believe began in 2006.

And this is direct, one-on-one engagement with DEA registered distributors. And that's different from the distributor conference, which is a -- a number of DEA registered distributors coming to a venue free of charge, you know, to -- to receive

presentations from DEA and to collaborate with DEA on -- on issues.

MS. ELLIS: Now marking for the record Exhibit 10. US-DEA-00 -- I'm sorry. US-DEA-00026803.

(Deposition Exhibit 10 was marked for identification.)

BY MS. ELLIS:

Q. Is this also a document that you reviewed in preparation for today's testimony?

A. It is.

Q. And this is dated December 20th, 2016?

A. Correct.

Q. What is this e-mail and its attachment?

A. This document actually -- the e-mail that's on the front page would have been from the GAO audit liaison team sending what is an update memorandum to our counterparts over at GAO.

Q. So is this an -- a subsequent update to the one that we just discussed?

A. Correct. In fact, on the first paragraph, it said "DEA provided its previous

status response on April 27th, 2016. And that's what this Exhibit 9 was.

Q. And what is the date of the letter attached to that e-mail?

A. It's December 20th, 2016.

Q. I'll direct you to the second page of the letter under Heading 2.

Is this an additional update as to what the DEA was doing in response to the GAA -- GAO's recommendation that the DEA provide more specific guidance to distributors with respect to their roles and responsibilities for suspicious order monitoring?

A. Yes. This would have included things that the agency was doing in an attempt, and as the last paragraph reads, based on the -- the preceding three paragraphs, requesting closure of the recommendation, based on this -- the preceding information.

Q. And I forgot to ask you.

In that previous Exhibit 9, did the DEA also request closure of the recommendation?

A. It did.

Q. Did the DEA feel at that time it had done -- did the DEA -- strike that.

Why did the DEA request closure of the recommendation in Exhibit 9 or at the time of Exhibit 9?

A. DEA reported in its response that it: "request closure of this recommendation based upon DEA's actions to obtain input from distributors and associations representing distributors. DEA will continue collaborating with these businesses and associations through regularly scheduled conferences and by working with NABP and the coalition of stakeholders to provide ongoing guidance to distributors regarding their roles and responsibilities for monitoring and reporting suspicious orders."

Q. And you were just reading from the document, Exhibit 9, right?

A. Correct.

Q. Now, in Exhibit 10, did the DEA also request closure of this recommendation?

A. It -- it did -- or we did, yes.

Q. What did -- what did you base that request on?

A. It actually looks very similar to the -- to the preceding update. So we -- I'll read it for the benefit of the group.

"DEA requests closure of this recommendation based upon DEA's actions to obtain input from distributors and associations representing distributors. DEA will continue collaborating with these businesses and associations through regularly scheduled conferences and provide ongoing guidance to distributors regarding their roles and responsibilities for monitoring and reporting suspicious orders."

Q. In addition to the efforts described in Exhibit 9, it appears that, in the third paragraph of Exhibit 10, beginning with "DEA has continued to work with distributors," there is the description of two additional conferences in 2016; is that right?

A. Correct.

Q. Could you read that aloud for the jury, please.

A. Sure.

"DEA has continued its work with distributors and associations by meeting with industry upon request and providing guidance and discussion related to suspicious orders. DEA held two distributors and one reverse

distributors conference in 2016. These conferences provided DEA with an excellent opportunity to engage its distributor registrants, attachment 4, about their roles and responsibilities for monitoring and reporting suspicious orders. DEA plans to host yearly training for distributors and reverse distributors, which will answer questions on these issues."

Q. I want to direct you to Table 21 that you discussed earlier in Exhibit 3. And that is on page --

A. 66?

Q. -- 66 -- thank you -- of the report.

In your earlier testimony, I believe you made the -- you clarified to say that the GAO's recommendation, as you understood it, was based on the response outlined in this table; is that right?

A. Yes. And some -- and some of the -- the -- they had an open-ended question, and then they had objective measures. And Table 21 was representing answers to objective measures in their survey.

Q. And in Table 21, this reflects that

there were 77 total responses from distributors; is that right?

A. Yes. I see one other thing that -- on this table representing distributors saying that there may have been 78 responses. But yes, 77 or 78 of the 200 that were -- that received the opportunity to respond to their survey.

Q. And you said a few moments ago that there's between, now, 715 to 750 distributors.

Was that number different at the time that this report was issued?

A. Yeah. The -- the number that's used in the report is I believe 954. And I believe the distinction there -- because I didn't go back and look at where we were in 2014. But I believe the difference is I'm talking about controlled substance distributors.

We also have a population of registrants that are involved in the distribution of List I chemicals. So I'm excluding the List I chemical population from my numbers.

Q. Would the number -- what would the number of controlled substances distributors

have been around the time that this report was issued, if you know?

A. I think it would have been comparable to what -- the numbers that we have now. I don't think we've seen any drastic changes in the size of our registrant population for DEA-registered distributors.

Q. So directing your attention back to Table 1.

Of those that responded to the survey -- let's look at this first line here.

Here you see the 77 responses, correct, is in respect to the DEA's Know Your Customer guidance, right?

A. Yes.

Q. Okay. And what is the total number of distributors that they said -- that thought that the DEA's feedback was very or moderately helpful?

A. So it's about two --

MS. MONAGHAN: Object to form.

THE WITNESS: It's approximately two-thirds of the registrants that did respond to this question indicated that they found DEA's guidance to be very or moderately

helpful.

BY MS. ELLIS:

Q. A majority.

A. A majority, yes.

Q. And how many, according to this chart, found that it was only slightly or not helpful at all?

MR. MASTERS: Object to form.

MS. MONAGHAN: Object to form.

THE WITNESS: The number here is 28 of 77.

BY MS. ELLIS:

Q. I want to direct your attention to Page 6 of Exhibit 3.

Earlier I believe you read for the record the sentence starting the second paragraph with "We also obtained documents from"?

A. Yes.

Q. Were -- were you personally involved in that process?

A. No.

Q. Are you -- and I believe you testified that you're not aware of who at the DEA was involved in that process?

A. That is correct. I'm not aware.

Q. Do you know what occurred during that meeting as far as the feedback that was solicited from the DEA by the GAO?

A. There were probably multiple meetings. But I'm not familiar with what transpired during each of those meetings.

Q. Do you know if the DEA had any feedback into who would -- who the participants in the survey would be?

MS. MONAGHAN: Object to form.

THE WITNESS: I have reason to believe that the people who would have been involved are no longer with the agency. So I -- I don't really have a good way of trying to reconcile that.

BY MS. ELLIS:

Q. So you don't know if the DEA had input into who the participants in the survey were?

A. Oh.

MS. MONAGHAN: Objection. Form.

THE WITNESS: I do believe we had input as to who would be participating in those meetings, yes.

BY MS. ELLIS:

Q. Do you know if the DEA had input into what the survey questions would be?

A. No. We did not have access to the questions.

Q. Do you know if the DEA had input into which states would be selected for participation in the survey?

MS. MONAGHAN: Object to form.

THE WITNESS: I don't know the answer to that question.

BY MS. ELLIS:

Q. Do you know of anyone at the DEA who -- who would know the answer to that question besides you?

A. I believe the people who would know, like I said previously, have since retired. So I don't -- I don't know of anybody.

Q. Do you know when the DEA first learned that the GAO was working on this report?

A. Go back and see if I can find it in the -- I'm sorry. I don't know the answer to that question.

Q. Are you aware of whether the GA

[sic] solicited input from registrants into the content of the survey?

MS. MONAGHAN: Object to form.

THE WITNESS: I don't know the answer to that question, no.

BY MS. ELLIS:

Q. Would that surprise you?

MR. MASTERS: Objection.

THE WITNESS: Yes. That would probably surprise me a little bit.

BY MS. ELLIS:

Q. Are you aware that the GAO solicited input into this report and the survey as early as July of 2013 --

MS. MONAGHAN: Object to form.

MR. MASTERS: Object to form.

BY MS. ELLIS:

Q. -- from registrants?

A. Can you repeat that.

Q. Are you aware that the GAO solicited input into the survey and report from registrants as early as July of 2013?

MS. WAITES: Objection. Foundation.

MR. MASTERS: Objection. Scope. Objection. Form.

THE WITNESS: And the answer is no.
BY MS. ELLIS:
Q. Are you aware that in August of 2013 the GAO participated in a conference call with the HDMA staff regarding this report?
MS. WAITES: Objection. Foundation.
MR. MASTERS: Objection. Scope. Objection. Form.
THE WITNESS: No. I am not aware.
BY MS. ELLIS:
Q. What is the HDMA; do you know?
MS. WAITES: Objection. Scope.
MS. MONAGHAN: Objection. Scope and form.
THE WITNESS: HDMA is now HDA. And I believe they're the Healthcare Distributor Alliance.
BY MS. ELLIS:
Q. Are you aware that this report by the GEO -- GAO -- pardon me -- incorporated the feedback from certain industry associations?
MS. WAITES: Objection. Foundation.
MS. MONAGHAN: Objection. Form and foundation and scope.
MR. MASTERS: Objection. Vague.

THE WITNESS: Can -- can you repeat that question.

BY MS. ELLIS:

Q. Yes. We'll just go to the document.

Let's go back to the summary page in Exhibit 3. It's the second page of the document.

The last sentence on the left-hand side says: "The" GEO [sic] "administered nationally representative web-based surveys to DEA-registered distributors, individual pharmacies, chain pharmacy corporate offices, and practitioners. GAO also interviewed officials from DEA, 26 national associations and other nonprofits and 16 government agencies in four states."

You see that.

A. Yes, I do.

Q. Are you aware of which associations and nonprofits those were?

A. I believe they were listed as potential -- oh, no, they weren't listed. No. So I don't know which -- which associations.

Q. So you don't to know if the HDMA or now called the HDA was one of the participants

in the study?

MS. MONAGHAN: Object to form and foundation.

THE WITNESS: I don't know. But I had reason to believe that they certainly would have been one of the associations.

BY MS. ELLIS:

Q. Why is that?

MS. MONAGHAN: Object to form.

THE WITNESS: HDA represents manufacturers and distributors of controlled substances. They are obviously an important association that we need to be working with.

And during my time as the head of our congressional affairs section, I -- I knew that they were on Capital Hill talking extensively to members of congress about their representatives' concerns over the amount of communication that they had with DEA.

BY MS. ELLIS:

Q. You said they were on the hill talking about their representatives' concern over the amount of communication that they had with the DEA.

What do you mean?

MS. MONAGHAN: Object to form. Scope.

THE WITNESS: So HDMA, HDA is a -- is a lobbying firm that represents the interests of -- of their clients on Capital Hill. And they were very vocal. And they've actually testified alongside DEA witnesses at hearings in which these -- these issues were brought up in terms of communication with the agency.

BY MS. ELLIS:

Q. Do you understand that they've tried to influence the way the DEA communicates with registrants?

MR. MASTERS: Object to form. Object to scope and foundation.

MS. WAITES: Object to scope and foundation.

THE WITNESS: Yes.

(Deposition Exhibit 11 was marked for identification.)

BY MS. ELLIS:

Q. I'm handing you, for the record, what's been marked as Exhibit 11, Bates numbered page MCKMMDL 00538072.

What is the subject line of the e-mail that you have in front of you?

A. "Inquiry from Government Accountability Office Regarding Distributor Interaction With DEA."

Q. Could you read the first sentence of the second paragraph, please.

A. "In August 2013, HDMA staff participated in a conference call with the GAO team tasked with pulling this report together. During this" -- I'm sorry.

Did you say --

Q. You can go on.

A. "During this meeting, HDMA staff gave a general overview of the industry's efforts to prevent diversion." At that -- "At the time we furnished them with testimony we provided to the Energy and Commerce Committee as well as the list of questions we had submitted DEA seeking further clarity on suspicious order monitoring and due diligence protocols."

Q. The next paragraph starts with "Specific follow-up questions from the" GE -- "GAO."

Could you read that, please, for the jury.

A. "We are preparing the survey questionnaire now and planning our sampling methodology and have a couple of questions we'd like your input on. A, if an individual DEA-registered distributor location received our survey, how likely would they be willing and able to complete it? We have heard, for example, that chain drug stores would likely not want their individual stores to respond to our survey. Instead they prefer (insist on) sending one corporate response. B, do the individually registered locations have direct interaction with DEA and/or other federal agencies; or is that more likely to happen at the corporate level?"

Q. And who is on the To line of this e-mail there at the top?

A. I see a representative from AmerisourceBergen, a individual from Cardinal Health, individual from Smith Drug, another Cardinal Health individual, somebody from Mutual Drug, somebody from HD Smith, somebody from McKesson, and another individual from

AmerisourceBergen.

Q. Are the companies that you just named, are you aware that those are registrants of the DEA?

A. Yes.

MS. WAITES: Objection. Scope.

THE WITNESS: Yes.

BY MS. ELLIS:

Q. And who's the From line there on that e-mail?

A. It is from Pat Kelly, who is with HDA.

Q. And what's the date on that e-mail?

A. February 20th, 2014.

Q. Are you aware if the DEA was asked for input on these questions around February 20th, 2014?

A. I am --

MS. MONAGHAN: Object to form.

THE WITNESS: I am not aware.

BY MS. ELLIS:

Q. Do you know if they were?

A. I don't know.

Q. You mentioned earlier what the DEA probably would have a series of conversations

with the GA -- GAO about this survey and the report, correct?

A. Yes.

Q. But you don't know when the dates of those would have been?

A. No. And I -- I imagine that those conversations would have been through the audit liaison section, which would have not really been part of my involvement at the time.

Q. Was the DEA invited to be at any of the meetings where the GAO solicited input from industry representatives?

MR. MASTERS: Objection. Foundation.

THE WITNESS: I don't know.

BY MS. ELLIS:

Q. Was the G -- was the DEA privy to the attendee list of any of the industry representatives that were participants in these meeting with the GAO?

MR. MASTERS: Objection. Form. Foundation.

THE WITNESS: My understanding is that DEA provided access to the CSA registration database. And that's the basis by

which GAO decided what their generalizable sample would be for purposes of administering the survey.

BY MS. ELLIS:

Q. So the entire database?

A. Correct.

Q. Not necessarily -- that would not be the specific list of who participated in the discussions with the GAO, correct?

MS. MONAGHAN: Object to form.

THE WITNESS: I -- I don't know the answer to that.

BY MS. ELLIS:

Q. Do you know who Rob Giacalone is?

A. No, I don't.

(Deposition Exhibit 12 was marked for identification.)

BY MS. ELLIS:

Q. Handing you what's been marked for the record as Exhibit 12.

Are you aware that the GAO held a meeting with industry representatives, including CSA, registrants in October of 2014?

MS. MONAGHAN: Object to form and foundation.

THE WITNESS: I am not, no.
BY MS. ELLIS:
Q. Would you read the first two sentences of the top of that e-mail for me, please.
A. Starting with "I'll ask Carl"?
Q. Yes.
A. "I'll ask Carl. As to HDMA, here are my thoughts."
Keep going.
Q. Yes, please.
A. Okay. "First, in my discussions with HDMA, they have told me that they were involved in helping to create the survey. So I'm assuming they have already provided their input to the GAO. Second, not sure if this meeting at NASCSA is just for industry (and not trade groups) given it's targeted specifically towards industry representatives. I can ask HDMA if they are going/got an invitation."
Keep going?
Q. Sure. Go ahead.
A. "Lastly, not sure we want Linden there at this event if we're trying to keep a low profile (and not sure he can go without

specifying for whom he is attending)."

Keep reading?

Q. Just go ahead and --

A. Okay.

Q. -- read the next two sentences.

A. "My overall concern with this is that we got burned before with the GAO. And I'm not sure how much we want to be perceived as being on the front end with them. I think we've worked towards coordinating a common theme from our industry colleagues (via our work groups, Purdue, et cetera. Just not sure the downside of the potentially irritating DEA is worth the added benefit of showing up at this meeting where DEA reps most likely will be present at the NASCSA meeting. If you think other" -- "otherwise, let's decide who should go. Thanks, Bob."

Q. Do you know if DEA reps were present at that NASCSA meeting?

MS. WAITES: Objection. Scope.

MS. MONAGHAN: Objection. Foundation and form.

THE WITNESS: I don't. I don't know the answer.

BY MS. ELLIS:

Q. Do you know whether there was any concerted effort by registrants to influence the GAO's report?

MR. MASTERS: Objection. Form. Foundation. Scope.

MS. WAITES: Objection. Calls for speculation.

THE WITNESS: I don't know.

BY MS. ELLIS:

Q. I want to direct your attention to Exhibit 8.

A. Was this -- was this part of Exhibit 12?

Q. It was.

A. Okay.

Q. It's an attachment to the e-mail. Thank you.

You discussed this exhibit earlier on the record.

Do you recall?

A. Yes.

Q. And what was -- what is this again?

A. This is a GAO summary. It's available on their web site. And it talks

about the -- the summary of the GAO report and then the status of recommendations. In this case, for this particular report, there were three recommendations. So below is the recommendation -- the three recommendations and their status.

Q. Recommendation 2, which we discussed in depth today, was for the DEA to provide more guidance to registrations -- or registrants and associations representing registrants regarding their roles and responsibilities for suspicious order monitoring, correct?

A. Yes. Yes.

Q. Back on the first page.

(Phone interruption.)

MS. ELLIS: I think we have -- you may want to mute your phone on the conference line.

(Discussion held off the stenographic record.)

MS. ELLIS: Can we go off the record for just one moment, please.

THE VIDEOGRAPHER: We are going off the record.

This is the end of Media Unit No. 2.

The time is 11:43.

(A short recess was taken.)

THE VIDEOGRAPHER: We are going back on the record.

This is the start of Media Unit No. 3.

The time is 11:44.

You may proceed, Counsel.

BY MS. ELLIS:

Q. We were just discussing Exhibit 8, which is the GAO summary available on their web site regarding the GAO report we've been discussing today.

I would like to direct your attention to midway through the first paragraph. And there is a sentence there starting with "Of those."

Do you see it?

A. Yes.

Q. Could you read that aloud, please.

A. "Of those registrants that have interacted with DEA, most were generally satisfied with those interactions. For example, 92 percent of distributors that communicated with DEA field office staff found

them 'very' or 'moderately' helpful. However, some distributors, individual pharmacies and chain pharmacy corporate office want improved guidance from and additional communication with DEA about their CSA roles and responsibilities. For example, 36 of 55 distributors commented that more communication or information from or interactions with DEA would be helpful. DEA officials indicated that they do not believe there is a need for more registrant guidance or communication."

Q. Do you understand that sentence to be the support for the GAO's Recommendation 2 in that report?

A. The --

MR. MASTERS: Objection.

THE WITNESS: The 36 of 55?

MS. ELLIS: Yes.

THE WITNESS: I don't have a way of knowing what GAO was thinking in terms of crafting their recommendations. So I can't answer your question.

BY MS. ELLIS:

Q. Let's look at the second paragraph. If you could read that aloud, please.

A. "Officials GAO interviewed from 14 of 16 state government agencies and 24 of 26 national associations said they interact with DEA through various methods. 13 of 14 state agencies and 10 of 17 national associations that commented about their satisfaction with DEA interactions said they were generally satisfied. However, some associations wanted improved DEA communication."

Q. The next paragraph goes on to put a number on that, quote, some associations, doesn't it? The next sentence?

MS. WAITES: Object to form.

BY MS. ELLIS:

Q. Go ahead and read the next sentence for the jury.

A. Okay.

"Because the additional communication that four associations want relates to their members' CSA roles and responsibility, improved DEA communication with and guidance for registrants may address some of the associations concerns."

So yes to your question. Four is the number.

Q. So is it your understanding that Recommendation 2 was based, in part, on feedback from four associations?

MS. WAITES: Objection. Calls for speculation.

MS. MONAGHAN: Yeah. Objection. Form. Foundation.

THE WITNESS: Yeah. Like I said, I don't know what -- what specifically GAO was thinking here. But it certainly seems reasonable that -- that these concerns raised by these associations may have informed their decision making.

MS. ELLIS: I have no further questions at this time.

THE VIDEOGRAPHER: We are going off the record.

The time is 11:48.

(A short recess was taken.)

THE VIDEOGRAPHER: We are going back on the record.

This is the start of Media Unit No. 3.

The time is 12:05.

You may proceed, Counsel.

MR. MASTERS: We only have a few minutes. We'll be as brief as possible.

FURTHER EXAMINATION BY COUNSEL FOR CARDINAL HEALTH

BY MR. MASTERS:

Q. Earlier today you were asked some questions about HDA and HDMA?

A. Yes.

Q. Are you aware or have knowledge of HDA or HDMA's membership structure?

MS. WAITES: Objection. Scope.

THE WITNESS: No.

BY MR. MASTERS:

Q. Are you aware of any of its missions relating to and with respect to its representative members?

MS. WAITES: Objection. Scope.

THE WITNESS: No.

BY MR. MASTERS:

Q. You don't have any -- any knowledge about the activities that HDMA or HDA engages in other than the work that you mentioned on Capitol Hill?

MS. WAITES: Objection. Scope.

THE WITNESS: Correct.

BY MR. MASTERS:

Q. Earlier today, when the plaintiffs were questioning you, you were shown a document reflecting questions from the GAO. I -- I -- I can't recall the exhibit.

A. 11?

Q. 11. Yes. That's it. Exhibit 11.

And you were directed to some specific questions -- some specific follow-up questions from the GAO.

Is that -- do you recall that?

A. Yes.

Q. Do these follow-up questions from the GAO go to the substance of the survey questions or to the process by which the survey would be administered?

MS. WAITES: Objection. Vague. Calls for speculation. Scope.

THE WITNESS: I -- I actually don't know.

BY MR. MASTERS:

Q. Based on -- based on the plain language, are -- is the -- is the GAO requesting information about how to maximize the responsiveness of the survey?

Is that -- would that be a fair way to characterize what they're seeking here?

MS. WAITES: Objection. Calls for speculation. Scope. Foundation.

THE WITNESS: Based on what I'm reading in Question A, the only thing that seems to maybe address your question is how likely would they, who I -- I assuming are the distributors, to be willing to or able to complete the survey.

BY MR. MASTERS:

Q. Is there anything improper about the GAO soliciting input on how to maximize the responsiveness of their survey?

MS. WAITES: Objection. Calls for speculation.

THE WITNESS: No. But I don't -- I'm not even certain that was -- that's called into question is --

BY MR. MASTERS:

Q. You were also shown a document reflecting a communication from DEA to GAO on December 20th, 2016. I believe it was Exhibit 10.

A. Yes.

Q. And on the second page of the letter -- I'll just go ahead and show you this -- this has some of my highlighting, but I want to direct you to the -- the paragraph -- the second paragraph of DEA's response states that: "The GAO survey was conducted in 2015 prior to new DEA leadership, including a new acting administrator and new management for the diversion control division. DEA's new management met with industry leaders on February 29th, 2016. Since then DEA has continued to work with the industry and improved communication on these issues."

Did I read that correctly?

A. Yes.

Q. In -- in the DEA's response to the GAO and the DEA's status report to the GAO, why did the DEA referenced [sic] new leadership and new management?

A. So there was a -- a recognition that in -- was it July of 2015 DEA got a new administrator. That was shortly after the former administrator, Michele Leonhart, retired. And one of Acting Administrator Rosenberg's first orders of business was to

work more in a collaborative fashion with our registrant community.

And so, in -- in -- along that side, he also decided to identify a new person that would run the diversion control program. And that resulted in the former head of diversion retiring.

Q. And this introduction of new management and new leadership in the DEA Office of Diversion Control and at the DEA resulted in improved communications on these issues, fair?

MS. WAITES: Objection. Mischaracterizes prior testimony.

THE WITNESS: The February 29th, 2016 meeting was a listening session. So this was our opportunity to basically hear from our trade associations as to things that they wanted to communicate with DEA about.

BY MR. MASTERS:

Q. And the DEA's new management felt that that was a priority?

A. That was something we absolutely wanted to do, yeah.

And I would say that, under the leadership of Acting Administrator Rosenberg,

that was a priority, yes.

Q. You also mentioned the distributor initiative as one of the ways in which the DEA communicates in a one-on-one basis with registrants, correct?

A. Yes.

Q. When was the last time that the DEA held a distributor initiative briefing with Cardinal Health?

MR. SMITH: Objection. Scope.

THE WITNESS: I don't know.

BY MR. MASTERS:

Q. When was the last time that the DEA held a distributor initiative briefing with AmerisourceBergen Drug Corporation?

MS. WAITES: Objection. Scope.

THE WITNESS: Same answer. I don't know.

BY MR. MASTERS:

Q. When was the last time the DEA held a distributor initiative -- initiative briefing with McKesson?

MS. WAITES: Objection. Scope.

THE WITNESS: And I'll -- I'll ask -- I don't know the answer.

But as a point of clarification, are we talking about an individual McKesson registration location, or are we talking about the corporation at large, which would encompass all their registrations?

BY MR. MASTERS:

Q. We're talking about the -- the distributor initiative briefing.

A. Yeah. Because that's done at a -- at a registrant-specific location. So I don't know the answer to your question.

But just as a point of clarification, if -- if each of these distributors have 20-plus distribution locations, we wouldn't necessarily do the distributor initiative with the corporation at large; it would generally be done with each individual location.

Q. Are you aware that distributor initiative briefings with the corporation at large were, in fact, held in 2005 with Cardinal Health, AmerisourceBergen and McKesson?

MS. WAITES: Objection. Foundation. Scope.

And after this, we're going to stop

questions, both because you're out of time, this is someone else's topic, and we said that we are not going to talk about individual meetings with distributors.

So --

MR. MASTERS: My --

MS. WAITES: If you have another wrap-up question or two, I'll allow it. But we're not going to continue with this line of questioning.

MR. MASTERS: My understanding from the authorization on this topic that -- that the witness would be off -- prepared to talk about the foundation -- or the basis of the DEA's response to the GAO in its draft -- when -- when it provided the draft report.

And one of the responses that the GA -- that the DEA gave in its report was, in emphasizing the communication, they referenced the distributor initiative briefings that began in 2005. And I'm simply probing the basis for -- for that statement.

MS. WAITES: We've been very clear that these depositions are not going to cover specific individual meetings. And if you

wanted to cover that, the appropriate person would have been -- would have been Mr. Provosnik.

So this line of questioning is certainly not appropriate for Mr. Strait. If you have another question regarding the GAO report, I'm fine with that. But you're also out of time.

BY MR. MASTERS:

Q. One final question: Counsel for plaintiffs at -- at Exhibit 9, I believe it was, reviewed a status report from April 27th, 2016, in which the DEA listed a number of communications that it -- or a number of efforts that it took to comply with the GAO's recommendation.

And I just want to confirm for the record that the GAO, in response to this letter, did not close the recommendation, correct?

A. They did not close the recommendation despite our request that they do so.

Q. And in -- and in June of 2016, the GAO stated that additional written guidance is

still -- has still not occurred and is -- and is needed in order to satisfy and close the recommendation, correct?

MS. WAITES: Objection. Misstates the document.

THE WITNESS: I would just refer you to the -- the plain language in -- in Exhibit 8, which talks about the status as indicated by GAO on their web site. And I can read that if you'd like.

BY MR. MASTERS:

Q. Which -- which is still open, correct?

A. It is still open, yes.

MR. MASTERS: No further questions. Thank you.

THE VIDEOGRAPHER: We are going off the record.

The time is 12:15.

(Discussion held off the record.)

THE VIDEOGRAPHER: We are back on the record.

The time is 12:16.

We are off the record at 12:16 p.m.

And this concludes today's testimony

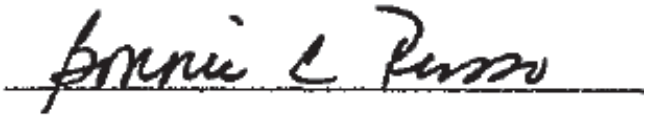
given by Matthew Strait.

The total number of media units used was three and will be retained by Veritext Legal Solutions.

(Whereupon, the proceeding was concluded at 12:16 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.



Notary Public in and for
the District of Columbia

My Commission expires: June 30, 2020

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

June 5, 2019

To: Natalie A. Waites

Case Name: In Re: National Prescription Opiate Litigation v.

Veritext Reference Number: 3404564

Witness: Matthew Strait Deposition Date: 5/31/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3404564
CASE NAME: In Re: National Prescription Opiate Litigation v.
DATE OF DEPOSITION: 5/31/2019
WITNESS' NAME: Matthew Strait

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

_____ _____
Date Matthew Strait

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3404564
CASE NAME: In Re: National Prescription Opiate Litigation v.
DATE OF DEPOSITION: 5/31/2019
WITNESS' NAME: Matthew Strait

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

_____ _____
Date Matthew Strait

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 3404564

PAGE/LINE(S) / CHANGE /REASON

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_____ _____

Date Matthew Strait

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____

DAY OF _____, 20_____ .

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Notary Public

_____

Commission Expiration Date

d

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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